

Applicant responds to the July 15, 2003 non-final office action in this application as follows:

1. Claim 11 have been amended so that it cannot be considered to be a substantial duplicate of claim 1. With such an amendment to claim 11, claim 12 (claim 12 is dependant upon claim 11) cannot be considered to be a substantial duplicate of claim 9.

Use of the word "direct" in claim 11 is supported by at least page 21, line 12 of the specification and by page 23, line 12 of the specification.

Additionally, use of the phrase "a sympathetic ganglion which innervates the thyroid" in claim 11 is supported by at least original claim 4.

2. Claim 1 has been amended to a claim scope which page 3 of the office action states is a claim scope which is an enabled claim scope: a method for treating thyroid disorders by direct administration of a botulinum toxin to the thyroid. Claim 4 has been cancelled. Claims 6-7 are dependant upon claim 1. Thus, the section 112(1) rejection of claims 1, 4 and 6-7 should be withdrawn.

3. Claim 6 has been amended by deleting the word "about". Additionally, claim 6 has been amended to clarify that "U/kg" means "U/kg of patient weight". This amendment to claim 6 is supported by at least page 27, line 28 of the specification. Hence the 112(1) rejection of claim 6 should be withdrawn.

4. Biglan discusses use of a botulinum toxin to treat the eyelid retraction symptom of Graves' disease (caused by a thyroid disorder) by injecting the toxin into periorbital muscles. Biglan does not disclose, teach or suggest injecting a botulinum toxin into a thyroid gland or into a sympathetic ganglion which innervates a thyroid gland. Thus, the claims, as amended are not anticipated by

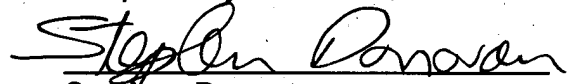
Biglan, and the 102(b) rejection of claims 1 and 6-12 over Biglan should therefore be withdrawn.

5. Regarding the seven (claims 1-7 and 9-12 are rejected by the office action twice over the same U.S. patent 6,524,580) obviousness-type double patenting rejections, seven terminal disclaimers are enclosed. Hence all of these rejections should be withdrawn.

6. Applicant hereby cancels claims 4 and 6 without prejudice to further prosecution at a later date.

All issues raised by the Office Action have been addressed. Reexamination, reconsideration and allowance of claims 1, 3, 5-7 and 9-12 is requested.

Respectfully submitted,


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CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

I hereby certify that this Response to Office Action and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date October 22, 2003 in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV295682435US addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Susan Bartholomew
Name of person mailing paper


Signature of person signing paper

Date: October 22, 2003